12/3/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Mid-Atlantic Region 595

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (201) 331-2907
November 24, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
Mr. Jonathan Metsch, CEO
Jersey City Medical Center
50 Baldwin Avenue
Jersey City, New Jersey

FILE NO.: 98-NWJ-06
Inspection ID NO.: 118414003

Dear Mr. Metsch:

Your facility was inspected on October 23, 1997 by a representative from the State of New Jersey Radiation Control Program under contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

- The interpreting physician, [redacted] is unqualified to interpret mammograms due to the lack of both board certification from any of the approved boards and two months full-time training in the interpretation of mammograms. Effective immediately, Dr. Sabbar must stop independent reading and interpreting of patient mammograms until he can document board certification from any of the approved boards (copy of Board Certificate or letter from the board) or document two months full-time training in the interpretation of mammograms (letter from residency program or documents to show 280 hours of CEUs).

The specific deficiencies noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. These deficiencies may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliances that were listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliances are:

- [redacted] did have documentation to demonstrate that he meets the initial training requirement of 40 hours of continuing medical education in mammography.

- [redacted] did have documentation to demonstrate he meets the requirement of having read and interpreted mammograms from the examination of at least 240 patients in a 6 month period prior to independent interpretation of mammograms.

- [redacted] did not have the documentation to demonstrate that he meets the requirement of interpretating an average of 40 mammograms per month in the 24 month period prior to the inspection.

The above identifications of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.

- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.

- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

You should notify this office in writing within 15 working days of receipt of this letter of:

- the specific steps you have taken to correct all of the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper recordkeeping procedures, if the noncompliances that were found relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Please direct your reply to Rosa L. Brown, Compliance Technician, Food and Drug Administration, New Jersey District, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054. Also, send a copy to the State Radiation Control Office listed below.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent requirements. You may choose to address both FDA and State requirements in your response.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Heyward L. Rourk, Regional Radiological Health Representative at (410) 962-3591.

Very truly yours,

Douglas I. Ellsworth

DOUGLAS I. ELLSWORTH
District Director
New Jersey District Office

RLB/

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